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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/340,664	11/16/1994	KAARE M. GAUTVIK	FORSK3.0001	5529

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/340,664	GAUTVIK ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31 and 33-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31 and 33-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/2005 has been entered.

Claims 31 and 33-42 are pending and under consideration.

New rejections apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 36 has been amended to recite that the claimed preparation is "free of human derived proteins and human infections agents". In the response filed 12/28/2005, applicant states that support for the phrase flows from the disclosure that the described hPTH is not isolated from human sources. The Examiner disagrees. Looking to the specification of U.S. Patent No. 5,420,242, of which this case is a divisional, and thus should have an identical specification, it can bee seen at column 1 that it is disclosed that:

> "Human parathyroid hormone has a relatively small molecular weight, which has made it possible to synthesize the peptide chemically by the sequential addition of amino acids. Thus, parathyroid hormone is commercially available, but in very small quantities at high cost. As a result, there is no human parathyroid hormone available at a reasonable price to supply the many potential medical, agricultural and industrial applications. "

Thus, the Examiner concludes that the problem that was intended to be solved by the instant invention was *not* the issue of presence of human or human-derived proteins, but rather the high cost of chemically synthesizing hPTH. Further, there is no disclosure in the specification as originally filed of any disadvantage to the chemically synthesized hormone *other* than cost; there is no disclosure that such a chemically synthesized hormone would have any biologically undesirable property. Although the absence of human proteins other than hPTH would be inherent to production of the hormone in *E. coli* or yeast, such was not considered to have been a problem to be solved, especially since at least some of the prior art is similarly free of any human proteins, having been the result of chemical synthesis.

The newly recited recitation in claim 36 that the claimed protein "does not contain chemically modified amino acids" constitutes new matter. It is noted that applicants allege that the disclosure of such is inherent to the disclosure that the claimed protein is recombinantly made, and not chemically synthesized. However, this is not persuasive because: (a) it has not been established on the record that chemically synthesized hPTH has any such "chemically modified" amino acids, and in fact, (b) the specification as filed, as quoted above, does not evince conception of this feature; the sole stated advantage to recombinant production is alleged to be cost. The *ex post facto* assertion that an inherent property of the hormone was conceived to be the invention, is not evidence of conception of this feature.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 33-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because hPTH is a human derived protein. Therefore, it is impossible to have a preparation of hPTH that is free of human derived proteins.

Claim 36 is further indefinite because the preamble indicates the claimed subject matter to be "A hPTH (1-84) preparation", whereas part (b) of the claim has been amended to indicate that "said hPTH (1-84) is free of human derived proteins. Accordingly, it cannot be determined whether or not the claimed *preparation* is free of such proteins.

Rejections over Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C.. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 36-42 remain rejected under 35 U.S.C.. 102(b) as anticipated by Brewer et al., U.S. Patent Number 3,886,132 for reasons of record. Applicants argue that the rejection is removed by the amendments to claim 36. This argument has been fully considered but is not deemed persuasive because the amendment to claim 36 is indefinite under 35 U.S.C. §112, second paragraph. It cannot be concluded that the claimed preparation is free of all human derived proteins and human infections agents.

Claims 31 and 33-34 remain rejected under 35 U.S.C. § 102(b) as being unpatentable over Breyel et al. (3rd Eur. Cong. Biotech., cited by appellants).

Breyel et al. teach expression of mature hPTH in *E. coli*, see Summary, page 363. The protein was expressed and bacterial cell extracts assayed for activity, see page 366 for example. Said extracts would inherently be free of human derived proteins and human infections agents.

Applicants argue that Breyel does not teach intact hPTH(1-84), and refers to page 9, line 3 of the Board decision. This argument has been fully considered but is not deemed persuasive because: The rejection overturned by the Board was made under 35 U.S.C. §103(a), in view of Kaisha, which was cited for further purification of the protein. The instant rejection is made under 35 U.S.C. §102(b), for substantially different reasons. The rejected claims are drawn to "a preparation of intact hPTH". The Examiner interprets "preparation" as meaning "a composition *comprising*", as it must *clearly* allow other elements to be present (no crystallized protein is disclosed in the specification as filed). Given this, the cell lysate of Breyel is a composition that comprises at least *some intact hPTH.* Regardless of the argument that degradation occurs, there is no reason to expect, nor have applicants established fact or evidence to the effect that *all* of the protein will be efficiently degraded. The Examiner further notes the Board decision at page 3, where it was clearly stated that "We see no requirement in claims 33-35 that hPTH be secreted from the microorganism. Claim 33 simply requires hPTH be produced followed by the purification of hPTH as a substantially homogeneous protein." Note that claim 33 no longer requires purification as "a substantially homogeneous protein", thus the cell lysates of Breyel anticipate the claims.

The Examiner notes that it would indeed be improper for the Examiner to reinstate a rejection that had been reversed by the Board of Appeals and Interferences. However, that is not the case here, as the claims have been substantively amended since the Board decision.

Claims 31 and 33-34 remain and claims 36-41 are rejected under 35 U.S.C. § 102(b) as being unpatentable over Mayer et al. (EP 0 139 076, cited by appellants). Mayer et al. teach recombinant production of hPTH in *E. coli*, see page 9, first full paragraph for example, page 12 of the enclosed English-language translation. The protein was purified from the cells and shown to be biologically active. The preparation of Mayer et al. would inherently be free of human derived proteins and human infections agents. It is noted that deletion of the purity limitation from claim 36 necessitates adding claims 36-42 to the rejection.

Applicants argument of this rejection has been fully considered but is not deemed persuasive for reasons above regarding the Breyel rejection.

Claims 31 and 33-42 are rejected under 35 U.S.C. 102 (a), (b) and/or (f) as being anticipated over applicant's admission of the prior art. It is noted that deletion of the purity limitation from claim 36 necessitates adding claims 36-42 to the rejection.

Applicant's argument has been fully considered but is not deemed persuasive for reasons of record. It remains that applicant merely alleges that the art does not apply, and provides no fact or evidence.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C.§ 103, the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. §102(f) or (g) prior art under 35 U.S.C§ 103.

Claim 35 remains and claim 42 is rejected under 35 U.S.C. § 103 as being unpatentable over Breyel et al. (3rd Eur. Cong. Biotech., cited by appellants) or Mayer et al. (EP 0 139 076, cited by appellants), any reference of the three in view of Kaisha et al. (GB 2 092 596, cited by appellants), and Brewer et al., U.S. Patent Number 3,886,132.

Applicants argument has been fully considered but is not deemed persuasive for reasons of record. The Examiner notes that as long as *some* intact protein was produced, the rejection is proper. The presence of degradation products would not negate the presence of the claimed protein. Applicants have presented no facts or evidence to overcome this rejection. This rejection is not in conflict with the decision of the BPAI, as the claims have been amended, and do not require the removal of all other forms of the protein.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed

copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner